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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,249	09/29/2000	Kendall Wayne King	PC10555A	1131

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/03/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/676,249

Applicant(s)

WAYNE ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29May2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 18-33 is/are pending in the application.
- 4a) Of the above claim(s) 18-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1,2 and 5-11 is/are objected to.
- 8) ☒ Claim(s) 1-11, 18-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Applicants' Response to Restriction, received 29May2002, paper#10, is acknowledged.
2. Applicants elect, with traverse, Invention I, claims 1-11, drawn to protein, classified in class 424, subclass 264.1.

Applicant's election with traverse is on the grounds that all of the groups of claim relate to the protein and uses thereof and would not present an undue burden on the Examiner. This is not found persuasive because while the searches for each group may overlap, they are not coextensive. The requirement is still deemed proper and is therefore made FINAL.

Claims 18-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 1-11 are under consideration.

### **Drawings**

4. This application has been filed with drawings which have been reviewed and approved by the Draftsperson.

### **Claim Rejections - 35 USC § 101**

5. 35 U.S.C. 101 reads as follows:  
Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.
6. Claims 1-4, 8, 10, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The claims are drawn to a protein comprising all or fragments of SEQ ID NO:4 or SEQ ID NO:2. There is no recitation that the proteins are isolated/purified. Therefore, the claims read on products of nature, i.e., proteins within *M. hyopneumoniae*.

**Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
8. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an immunogenic protein comprising SEQ ID NO:2 or a fragment, variant or derivative thereof.

The instant specification does not define or teach guidelines for determining variants or derivatives thereof. In addition, it is unclear if these terms are referring to only SEQ ID NO:2 or the entire immunogenic protein.

10. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

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in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 is drawn to a composition of comprising said protein of claim 1, a pharmaceutically acceptable carrier, and further comprising  $\geq 1$  polypeptide selected from the groups consisting of *M. pneumoniae* P46, P65, P97, and P102.

The instant specification teaches production of a fusion protein, thiodoxin-Mhp3, but does not teach any composition commensurate with the scope of the instant claim.

11. Claim 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a protein which “does not have a fatty acid acylated cystein followed by the amino acid sequence TrpAspLysGlu”. However, it is unclear what are the metes and bound of “followed”, i.e., immediately following, or within a nondesignated number of residues.

### Claim Objections

12. Claims 1, 2, and 5-11 are objected to because the claims contain an amino acid sequence, i.e., TrpAspLysGlu, without the required sequence identifier.

M.P.E.P. §2422.03, paragraph 9 recites:

37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the “Sequence Listing” by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as “residues 14 to 243 of SEQ ID NO:23” is permissible and the fragment need not be separately presented in the “Sequence Listing.” Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

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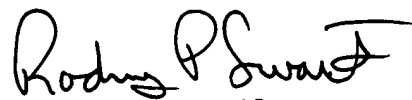
### Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER  
Art Unit 1645

October 2, 2002